pure enrichment

2 YEAR WARRANTY

# PUREPULSE

## TENS ELECTRONIC PULSE STIMULATOR


USER MANUAL
MODEL: PEPULSE

## CONTRAINDICATIONS

- Do not use this device on patients who have a cardiac pacemaker, implanted defibrillator, or other implanted metallic or electronic device because this may cause electric shock, burns, electrical interference, or death.
- Do not use this device on patients whose pain syndromes are undiagnosed.

## WARNINGS

- Do not apply stimulation over the patient's neck because this could cause severe muscle spasms resulting in closure of the airway, difficulty in breathing, or adverse effects on heart rhythm or blood pressure.
- Do not apply stimulation across the patient's chest, because the introduction of electrical current into the chest may cause rhythm disturbances to the patient's heart, which could be lethal.
- Do not apply stimulation over, or in proximity to, cancerous lesions.
- Do not apply stimulation when the patient is in the bath or shower.
- If you have one of the following conditions, please consult with your physician before purchasing or using this device:
    - Acute disease, malignant tumor, infectious disease, pregnancy, heart disease, high fever, abnormal blood pressure, lack of skin sensation, an abnormal skin condition, or any other condition requiring the active supervision of a physician.

## PRECAUTIONS

- Do not use this device while driving.
- Do not use this device while sleeping.
- Do not use this device in high humidity areas such as a bathroom.
- Keep the device away from wet, high temperature and direct-sunlight place.
- Keep this device out of reach of children.



## SAFETY WARNING

- Do not use the device around the heart, on the head, mouth, pudendum or blemished skin areas.
- Do not apply stimulation of this device in the following conditions:
    1. across the chest because the introduction of electrical current into the chest may cause rhythm disturbances to the heart, which could be lethal;
    2. over painful areas. Please consult with your physician before using this device if you have painful areas;
    3. over open wounds or rashes, or over swollen, red, infected, or inflamed areas or skin eruptions (e.g., phlebitis, thrombophlebitis, varicose veins). Apply stimulation only to normal, intact, clean, healthy skin;
    4. in the presence of electronic monitoring equipment (e.g., cardiac monitors, ECG alarms). The electronic stimulator may not operate properly when the electrical stimulation device is in use;
    5. while operating machinery, or during any activity in which electrical stimulation can put you at risk of injury;
    6. on children.

## BE AWARE OF THE FOLLOWING:

1. Consult with your physician before using this device. Stimulation with the device may:
    i. cause lethal rhythm disturbances to the heart in susceptible individuals;
    ii. disrupt the healing process after a recent surgical procedure;
2. Device is not effective for pain of central origin, including headache;
3. Device is not a substitute for pain medications and other pain management therapies;
4. Device has no curative value;
5. Device is a symptomatic treatment and, as such, suppresses the sensation of pain that would otherwise serve as a protective mechanism;

6. The long-term effects of electrical stimulation are unknown;
7. User may experience skin irritation, burns or hypersensitivity due to the electrical stimulation or electrical conductive medium (gel);
8. If the user has suspected or diagnosed epilepsy, the user should follow precautions recommended by his or her physician;
9. Use caution if the user has a tendency to bleed internally, such as following an injury or fracture;
10. Use caution if stimulation is applied over the menstruating uterus;
11. Use caution if stimulation is applied over areas of skin that lack normal sensation;
12. Stop using the device if the device does not provide pain relief;
13. Use this device only with the leads, electrodes, and accessories that the manufacturer recommends.
14. Do not share the use of the electrode pads with others.
15. Do not use the device while it's charging.
16. The device contains the lithium battery. If overheating of the device occurred during the charging, stop the charging or operation immediately and report to the seller.
17. Dispose of the battery-containing device according to the local, state, or federal laws.

- The long-term effects of electrical stimulation are unknown.
- Since the effects of stimulation of the brain are unknown, stimulation should not be applied across the head, and electrodes should not be placed on opposite sides of the head.
- The safety of electrical stimulation during pregnancy has not been established.
- Some patients may experience skin irritation or hypersensitivity due to the electrical stimulation or electrical conductive medium (gel).



- Patients with suspected or diagnosed heart disease should follow precautions recommended by their physicians.
- Patients with suspected or diagnosed epilepsy should follow precautions recommended by their physicians.
- Use caution if stimulation is applied over the menstruating or pregnant uterus.

## ADVERSE REACTIONS

- Patients may experience skin irritation and burns beneath the stimulation electrodes applied to the skin;
- Patients may experience headache and other painful sensations during or following the application of electrical stimulation near the eyes and to the head and face.
- Patients should stop using the device and should consult with their physicians if they experience adverse reactions from the device.

## ENVIRONMENTAL CONDITION FOR NORMAL WORKING, TRANSPORT STORAGE

- Normal working ambient temperature: 5~40°C
- Normal working ambient humidity: 15%~90% RH
- Store and transport ambient temperature: -25~70°C
- Store and transport ambient humidity: 0% ~90% RH
- Atmospheric pressure: (70~106) kPa

## SYMBOLS INTERPRETATION

| | | | |
|---|---|---|---|
|  | Fragile, handle with care |  | Type BF applied part |
|  | Keep the product in the dry place. Away from water and rain. |  | CAUTION, Avoid injury. Read and understand owner's manual before operating this product |
|  | Product package should be recycled. |  | Manufacturer |
|  | This way up |  | Unrecyclable |
|  | Date of manufacture | LOT | Batch code |
| SN | Serial number | IP22 | IP code of the device |

## SAFETY TEST STANDARDS

Medical Devices Directive 93/42/EEC

IEC 60601-1:2005+A1:2012/EN 60601-1:2006 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

IEC 60601-1-2:2007/EN 60601-1-2:2007 Medical electrical equipment - Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests

IEC 60601-2-10:2012/EN 60601-2-10:2000+A1:2001 Medical electrical equipment - Part 2-10: Particular requirements for the safety of nerve and muscle stimulators

IEC 60601-1-11:2010 Medical electrical equipment -- Part 1-11: General requirements for basic safety and essential performance -- Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment.

EN 980 Symbols for use in the labeling of medical devices

EN 1041 Information supplied by the manufacturer with medical devices

IEC/60601-1-6/ EN 60601-1-6 Medical electrical equipment Part1-6: General requirements for basic safety and essential performance – Collateral standard: Usability

IEC 60601-1-11/ EN 60601-1-11 Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in home healthcare environment

IEC 62304/ EN 62304 Medical device software - Software life-cycle processes

IEC 62366/ EN 62366 Medical devices – Application of usability engineering to medical devices

ISO 10993-1 Biological evaluation of medical devices Part 1: Evaluation and testing within a risk management process

## FCC NOTICE

**Model:** PurePulse TENS Electronic Pulse Stimulator (PEPULSE)

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

Pure Enrichment
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Santa Ana, CA 92704
pureenrichment.com

The product is protected against unauthorized use. DO NOT modify it without the authorization of the manufacturer, or the user's authority to operate could be voided.

**Note:** This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, used and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off an on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and the receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

## ELECTROMAGNETIC COMPATIBILITY

1. This product requires special precautions regarding electromagnetic compatibility (EMC) and needs to be installed and put into service according to the EMC information provided, and this unit can be affected by portable and mobile radio frequency (RF) communications equipment.
2. Do not use a mobile phone or other devices that emit electromagnetic fields, near the unit. This may result in incorrect operation of the unit.
3. Caution: This unit has been thoroughly tested and inspected to assure proper performance and operation!
4. Caution: This machine should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, this machine should be observed to ensure it operates properly in the configuration in which it will be used.



## ELECTROMAGNETIC COMPATIBILITY

<table>
<tr><td colspan="3">Guidance and manufacturer's declaration – electromagnetic emission</td></tr>
<tr><td colspan="3">The device is intended for use in the electromagnetic environment specified below. The customer of the user of the device should assure that it is used in such an environment.</td></tr>
<tr><td>Emission test</td><td>Compliance</td><td>Electromagnetic environment – guidance</td></tr>
<tr><td>RF emissions CISPR 11</td><td>Group 1</td><td>The device use RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.</td></tr>
<tr><td>RF emission CISPR 11</td><td>Class B</td><td rowspan="3">The device is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.</td></tr>
<tr><td>Harmonic emissions<br>IEC 61000-3-2</td><td>Not applicable (internal battery powered)</td></tr>
<tr><td>Voltage fluctuations/ flicker emissions<br>IEC 61000-3-3</td><td>Not applicable (internal battery powered)</td></tr>
</table>

## ELECTROMAGNETIC COMPATIBILITY

| Guidance and manufacturer's declaration – electromagnetic immunity | | | |
|---|---|---|---|
| The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment. | | | |
| Immunity test | IEC 60601 test level | Compliance level | Electro-magnetic environment - guidance |
| Electrostatic discharge (ESD)<br>IEC 61000-4-2 | ±6 kV contact<br>±8 kV air | ±6 kV contact<br>±8 kV air | Floors should be wood, concrete or ceramic tile. If floor are covered with synthetic material, the relative humidity should be at least 30%. |
| Electrical fast transient/burst<br>IEC 61000-4-4 | ±2 kV for power supply lines<br>±1 kV for input/ output lines | Not applicable<br>(internal battery powered) | Mains power quality should be that of a typical commercial or hospital environment. |
| Surge<br>IEC 61000-4-5 | ± 1 kV line(s) to line(s)<br>± 2 kV line(s) to earth | Not applicable<br>(internal battery powered) | Mains power quality should be that of a typical commercial or hospital environment. |
| Voltage dips, short interruptions and voltage variations on power supply | <5% UT<br>(>95% dip in UT)<br>for 0.5 cycle | Not applicable<br>(internal battery powered) | Mains power quality should be that of a typical commercial or hospital environment. |
| input lines<br>IEC 61000-4-11 | 40% UT (60% dip in UT) for 5 cycles<br>70% UT (30% dip in UT) for 25 cycles<br><5% UT<br><5% UT (>95% dip in UT) for 5 sec | | If the user of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterrupted power supply or a battery. |
| Power frequency (50Hz/60Hz) magnetic field<br>IEC 61000-4-8 | 3 A/m | 3 A/m | Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment. |
| NOTE UT is the a.c. mains voltage prior to application of the test level. | | | |

## ELECTROMAGNETIC COMPATIBILITY

| Guidance and manufacturer's declaration – electromagnetic immunity | | | |
|---|---|---|---|
| The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment. | | | |
| Immunity test | IEC 60601 test level | Compliance level | Electromagnetic environment - guidance |
| Conducted RF<br>IEC 61000-4-6 | 3 Vrms<br>150 kHz to 80 MHz | 3 Vrms | Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance<br>$d=1,2\sqrt{P}$<br>$d=1,2\sqrt{P}$ 80 MHz to 800 MHz<br>$d=2,3\sqrt{P}$ 800 MHz to 2,5 GHz<br>Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).<br>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range[b].<br>Interference may occur in the vicinity of equipment marked with the following symbol: |
| Radiated RF<br>IEC 61000-4-3 | 3 V/m<br>80 MHz to 2.5 GHz | 3 V/m | |



NOTE1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the device.

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

| Immunity test | IEC 60601 test level | Compliance level | Electro-magnetic environment - guidance |
|---|---|---|---|

| Recommended separation distances between portable and mobile RF communications equipment and the device. | | | |
|---|---|---|---|
| Rated maximum output power of transmitter (W) | Separation distance according to frequency of transmitter(m) | | |
| | 150 KHz to 80 MHz | 80 MHz to 800 MHz | 800 MHz to 2.5 GHz |

## ELECTROMAGNETIC COMPATIBILITY

| | | | |
|---|---|---|---|
| 0.01 | 0.12 | 0.12 | 0.23 |
| 0.1 | 0.38 | 0.38 | 0.73 |
| 1 | 1.2 | 1.2 | 2.3 |
| 10 | 3.8 | 3.8 | 7.3 |
| 100 | 12 | 12 | 23 |

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

## INTRODUCTION

Thank you for purchasing the PurePulse TENS Electronic Pulse Massager from Pure Enrichment. This safe and easy-to-use device delivers electric pulses to the muscles through the included electrode pads, which you place on your skin.

PurePulse is safe to use on muscles in the shoulders, waist, back, arms, and legs.

## FEATURES

- User-friendly LCD screen
- Dual channels allow for two different modes simultaneously
- 6 high-frequency stimulation modes
- Power: DC 6V, 4 AAA batteries
- Frequency: 62.5Hz
- Accessories included: 4 electrode pads, 2 electrode wires, 4 AAA batteries
- FDA-approved for your safety
- 2 Year Warranty - Satisfaction guranteed!



## TECHNICAL INFORMATION

| | | | |
|---|---|---|---|
| **Model/type** | PEPULSE | **Weight** | 137g |
| **Power supply** | 4 AAA batteries | **Automatic shutoff** | 15 minute |
| **Waveform and wave shape** | Single wave pulse | **Degree of protection against electric shock** | Type BF applied part |
| **Pulse duration** | 100-500μs (Microseconds) | **Type of protection against electric shock** | Internally powered equipment(Not applicable) |
| **Pulse frequency** | 1-62.5Hz (Hz=vibration per second) | **Grade of waterproof** | IP22 |
| **Output Voltage** | Max.30Vpp ±20% (at 500ohm load) | **Product life** | |
| **Treatment time** | 15 minutes | **Lifetime for electrode** | Storage for 2 years (no use), Times of reus-able: 30 times |
| **Output intensity** | 0 to 10 levels, adjustable | **Mode of operation** | Continuous operation |
| **Modes** | 3 auto modes | **Software version** | A0 |
| Note: Not intended to be sterilized. | | | |
| Not for use in an OXYGEN RICH ENVIRONMENT | | | |

## PRODUCT SPECIFICATIONS

### PROGRAMS

| Program | Pulse Rate (Hz) | Pulse Width (μs) |
|---|---|---|
| Mode 1 | 62.5 | 100~240 |
| Mode 2 | 1 | 500 |
| Mode 3 | 62.5 | 100~240 |

## OPERATING THE PRODUCT

### HOW TO SET UP AND USE YOUR PUREPULSE

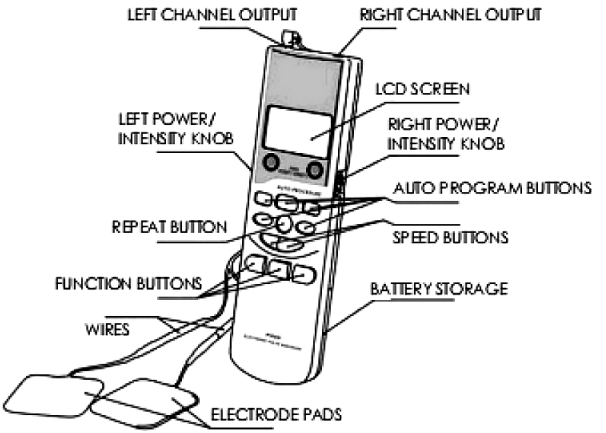
1. Install 4 AAA batteries into the device noting the positive and negative directions. Ensure both Power/Intensity Knobs are in the "OFF" position before installing batteries.
2. Connect the electrode pads to the wires. Plug-in the electrode wires into the controller via the Left Channel Output and Right Channel Output.
3. Attach the electrode pads to the desired treatment area(s).
4. Turn the Power/Intensity Knob to 1. The screen should show a "P". This means the device is ready to begin treatment.
5. Select an automated massage program by pressing one of the Auto Program Buttons. There are 6 auto stimulation programs designed for the various functions and parts of the body: Waist, Shoulders, Joints, Hand/Foot, Sole, and Repeat.
6. Press SPEED+ or SPEED- to adjust the speed; rotate the Power/Intensity Knobs to adjust the intensity.
7. In addition to the automated setting, you can also manually select 3 different types of massages by using the function buttons: Massage, Beat, Knead

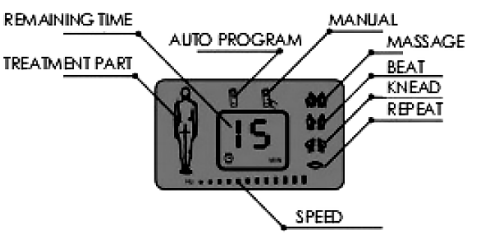


## CLEANING AND MAINTENANCE

Use water or a mild detergent soap to clean the device first. Then, use a dry cloth to wipe. Do not soak, get water in the buttons and battery compartment, or use any harsh liquids.

## PRODUCT DIAGRAM

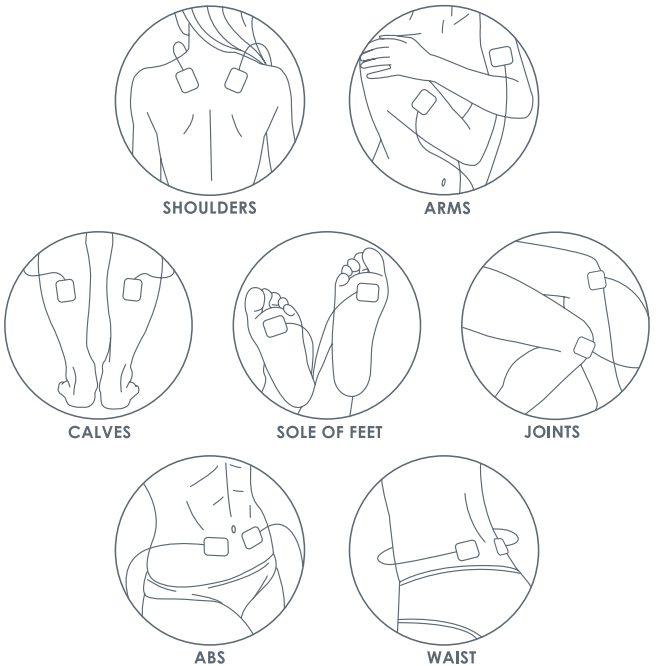


## ADDITIONAL NOTES AND BEST PRACTICES

- Start from the lowest speed and intensity, and then gradually adjust to a comfortable level on a scale from 1 to 10
- Recommended duration is 10-15 minutes for each treatment area
- 1-2 treatments recommended per area per day
- Be sure that the targeted area is free of dirt, perspiration, or any skin abrasions

## USE POSITION DIAGRAMS






## TROUBLE SHOOTING

If your device is not operating properly, please check it for the following problems or conditions. If you are still unable to solve the problem, please contact us for a replacement.

### Stimulation is weak or non-existent

PurePulse provides a strong and noticeable stimulation to your muslces. If the stimulation is weak or non-existent, review the following:

- Ensure skin is clean and that the pads are firmly stuck to the skin (see below if the pads are not sticking)
- Ensure the pads are not touching each other
- Double check that all wires are fully plugged into the device – disassemble the device and reconnect
- Both pads of the same wire are connected to your body

### Skin is getting irritated or turning red

If your skin is getting red or irritated, you are likely using too powerful of a setting or keeping it on too long in the same spot. Reduce and adjust usage.

### Device is not turning on

If the PurePulse's LCD is not turning on make sure the batteries are installed correctly. Replace the batteries if needed.

### Electrode pads are not sticking

If the electrode pads are not sticking, they need to be replaced. PurePulse electrode pads are designed to be used up to 30 times before replacement. However, skin type, product usage, and pad storage may impact the number of uses you get out of your pads. To extend the lifespan of your electrode pads, store them on their original plastic sheet after each use.

*Replacement pads can be ordered at pureenrichment.com*

## WARRANTY AND REGISTRATION INFORMATION

### Warranty Information

PurePulse comes with an industry-leading 2 Year Warranty that begins on the date of purchase.

The warranty applies to the TENS device and necessary parts and labor relating thereto. The warranty does not apply to damage resulting from failure to follow the operating instructions, accidents, abuse, alterations, or disassembly by unauthorized individuals.

### Product Registration

To ensure your full warranty and to receive product updates and streamlined customer support, remember to register your product at:

www.pureenrichment.com/productregistration

**ARE YOU 100% SATISFIED?**

If you have product questions or concerns, don't hesitate to contact us directly at:

Email: help@pureenrichment.com
Phone: (657) 275-3737
(Available Monday-Friday, 8am-5pm PST)

Pure Enrichment has an award-winning warranty, exchange, and customer service program that guarantees hassle-free solutions to any issue you might have within 24 hours!

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